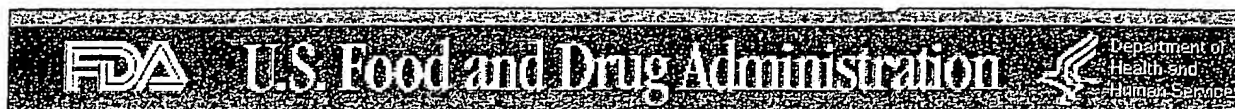


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## TITLE 21--FOOD AND DRUGS

## SUBCHAPTER H - MEDICAL DEVICES

PART 876 GASTROENTEROLOGY-  
UROLOGY DEVICES**Subpart A -- General Provisions**

- [§ 876.1](#) - Scope.
- [§ 876.3](#) - Effective dates of requirement for premarket approval.
- [§ 876.9](#) - Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act).

**Subpart B -- Diagnostic Devices**

- [§ 876.1075](#) - Gastroenterology-urology biopsy instrument.
- [§ 876.1300](#) - Ingestible telemetric gastrointestinal capsule imaging system.
- [§ 876.1400](#) - Stomach pH electrode.
- [§ 876.1500](#) - Endoscope and accessories.
- [§ 876.1620](#) - Urodynamics measurement system.
- [§ 876.1725](#) - Gastrointestinal motility monitoring system.
- [§ 876.1735](#) - Electrogastrography system.
- [§ 876.1800](#) - Urine flow or volume measuring system.

**Subpart C -- Monitoring Devices**

- [§ 876.2040](#) - Enuresis alarm.

**Subpart D -- Prosthetic Devices**

- [§ 876.3350](#) - Penile inflatable implant.
- [§ 876.3630](#) - Penile rigidity implant.
- [§ 876.3750](#) - Testicular prosthesis.

S/N 10/007,393

Amendment dated Sept 29, 2005

Office Action dated July 13, 2005

Exhibit 3

**Subpart E -- Surgical Devices**

- [§ 876.4020](#) - Fiberoptic light ureteral catheter.
- [§ 876.4270](#) - Colostomy rod.
- [§ 876.4300](#) - Endoscopic electrosurgical unit and accessories.
- [§ 876.4370](#) - Gastroenterology-urology evacuator.

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- § 876.4400 - Hemorrhoidal ligator.
- § 876.4480 - Electrohydraulic lithotripter.
- § 876.4500 - Mechanical lithotripter.
- § 876.4530 - Gastroenterology-urology fiberoptic retractor.
- § 876.4560 - Ribdam.
- § 876.4590 - Interlocking urethral sound.
- § 876.4620 - Ureteral stent.
- § 876.4650 - Water jet renal stone dislodger system.
- § 876.4680 - Ureteral stone dislodger.
- § 876.4730 - Manual gastroenterology-urology surgical instrument and accessories.
- § 876.4770 - Urethrotome.
- § 876.4890 - Urological table and accessories.

**Subpart F -- Therapeutic Devices**

- § 876.5010 - Biliary catheter and accessories.
- § 876.5030 - Continent ileostomy catheter.
- § 876.5090 - Suprapubic urological catheter and accessories.
- § 876.5130 - Urological catheter and accessories.
- § 876.5160 - Urological clamp for males.
- § 876.5210 - Enema kit.
- § 876.5220 - Colonic irrigation system.
- § 876.5250 - Urine collector and accessories.
- § 876.5270 - Implanted electrical urinary continence device.
- § 876.5280 - Implanted mechanical/hydraulic urinary continence device.
  
- § 876.5310 - Nonimplanted, peripheral electrical continence device.
- § 876.5320 - Nonimplanted electrical continence device.
- § 876.5365 - Esophageal dilator.
- § 876.5450 - Rectal dilator.
- § 876.5470 - Ureteral dilator.
- § 876.5520 - Urethral dilator.
- § 876.5540 - Blood access device and accessories.
- § 876.5600 - Sorbent regenerated dialysate delivery system for hemodialysis.
- § 876.5630 - Peritoneal dialysis system and accessories.
- § 876.5665 - Water purification system for hemodialysis.
- § 876.5820 - Hemodialysis system and accessories.
- § 876.5830 - Hemodialyzer with disposable insert (Kiil type).
- § 876.5860 - High permeability hemodialysis system.
- § 876.5870 - Sorbent hemoperfusion system.
- § 876.5880 - Isolated kidney perfusion and transport system and accessories.
- § 876.5885 - Tissue culture media for human ex vivo tissue and cell culture processing applications.
- § 876.5895 - Ostomy irrigator.
- § 876.5900 - Ostomy pouch and accessories.
- § 876.5920 - Protective garment for incontinence.
- § 876.5955 - Peritoneo-venous shunt.
- § 876.5970 - Hernia support.

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§ 876.5980 - Gastrointestinal tube and accessories.

§ 876.5990 - Extracorporeal shock wave lithotripter.

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

**Source:** 48 FR 53023, Nov. 23, 1983, unless otherwise noted.

Database Updated April 1, 2004

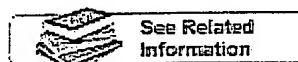
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[Code of Federal Regulations]  
[Title 21, Volume 8]  
[Revised as of April 1, 2004]  
[CITE: 21CFR876.5320]



TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H - MEDICAL DEVICES

PART 876 -- GASTROENTEROLOGY-UROLOGY DEVICES

## Subpart F -- Therapeutic Devices

Sec. 876.5320 Nonimplanted electrical continence device.

(a) *Identification.* A nonimplanted electrical continence device is a device that consists of a pair of electrodes on a plug or a pessary that are connected by an electrical cable to a battery-powered pulse source. The plug or pessary is inserted into the rectum or into the vagina and used to stimulate the muscles of the pelvic floor to maintain urinary or fecal continence. When necessary, the plug or pessary may be removed by the user. This device excludes an AC-powered nonimplanted electrical continence device and the powered vaginal muscle stimulator for therapeutic use (\$ 884.5940).

(b) *Classification.* Class II (performance standards).

Database Updated April 1, 2004

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Exhibit 5  
S/N 10/007,393  
Amdt dated 3/23/05  
Office Action dated 12/16/04